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No. 84-497

In the Supreme Court of the United States

OCTOBER TERM, 1984

LEE M. THOMAS, ACTING ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

UNION CARBIDE AGRICULTURAL PRODUCTS CO., ET AL.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR THE APPELLANT

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QUESTIONS PRESENTED

1. Whether a constitutional challenge to the data compensation and arbitration scheme of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(1)(D)(ii), is justiciable when the plaintiffs fail to show an actual injury that would be redressed by the requested relief.

2. Whether, if we assume the issue is justiciable, FIFRA's data compensation and arbitration provisions violate Article III of the United States Constitution because the awards made by the arbitrators selected under the statute are subject to review by an Article III court only on a showing of "fraud, misrepresentation, or other misconduct." 7 U.S.C. 136a(c)(1)(D)(ii).

3. Whether, if we assume the issue is justiciable and these provisions violate Article III, the plaintiffs are entitled to a judgment invalidating the entire scheme for consideration of previously submitted data rather than a judgment striking the limitation on judicial review.

PARTIES TO THE PROCEEDING

In addition to those named in the caption, the parties are: Abbott Laboratories, Ciba-Geigy Corporation, I.E. duPont De Nemours Company, FMC Corporation, Rhone-Poulenc, Inc., Rohm and Haas Company, Stauffer Chemical Corporation, Uniroyal, Inc., Velsicol Chemical Corporation and Zoecon Corporation. The following entities, originally parties to this action, were dismissed prior to final judgment: Ralston Purina Company, Salisbury Laboratories, Inc., Sandoz, Inc., Upjohn Company, and the National Agricultural Chemicals Association.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR THE APPELLANT

OPINION BELOW

The judgment and order (J.S. App. 1a-4a) of the district court is unreported. The prior opinion of the district court (J.S. App. 5a-20a) is reported at 571 F. Supp. 117.

JURISDICTION

The judgment of the district court (J.S. App. 21a-22a) was entered on August 7, 1984 and was amended (J.S. App. 1a-4a) on September 4, 1984. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on September 6, 1984 (J.S. App. 23a-24a). The jurisdictional statement was filed on September 27, 1984,

and the Court noted probable jurisdiction on November 26, 1984 (J.S. 64). The jurisdiction of the Court rests on 28 U.S.C. 1252.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III, Section 1, of the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, are reprinted at J.S. App. 27a-31a.

STATEMENT

1. Following the remand and reconsideration ordered by this Court on July 2, 1984,[1] the court below has again declared unconstitutional a key provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, the federal legislation regulating the marketing and use of pesticides. This Court directed reconsideration in light of its decision in *Ruckelshaus* v. *Monsanto Co.*, No. 83-196 (June 26, 1984) (*Monsanto*), a case in which the Court reviewed and sustained the constitutionality of FIFRA's data licensing and disclosure provisions. Under the statute, persons seeking to market a pesticide product in the United States must first obtain a registration from the Environmental Protection Agency (EPA). 7 U.S.C. 136a(a). The Administrator bases his determination to grant a registration, in part, on test data submitted or cited by the application for registration, data that generally include information on the chemical nature and structure of the pesticide as well as test results on the potential dangers of the product. Section 3(c)(1)

[1] *Ruckelshaus* v. *Union Carbide Agricultural Products Co.*, No. 83-1564.

(D) of FIFRA permits EPA to consider certain categories of health and safety data submitted by one applicant in support of the application of another company. 7 U.S.C. 136a(c)(1)(D). That Section also provides that the latter applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings.

Congress first required the registration of pesticides marketed in the United States in 1947,[2] in legislation that authorized the Secretary of Agriculture to set test data requirements for registration. Act of June 25, 1947, ch. 125, § 4(a), 61 Stat. 167.[3] It was not until 1972, however, that Congress addressed the question whether agency officials could consider data submitted by one registrant in reviewing a subsequent application by another person for the same pesticide. *Monsanto*, slip op. 2. After considerable debate, Congress amended the statute to authorize EPA to consider previously submitted data if the subsequent applicant offered to compensate the original data submitter and if the data were not protected from disclosure by Section 10(b) of the statute as "trade secrets." Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §§ 3, 10(b), 86 Stat. 979-980, 989. See *Monsanto*, slip op. 3-4. The amount of compensation would be determined either through negotiation between the parties,

[2] Under prior statutes, dating back to 1910, it was unlawful to manufacture and sell insecticides that were adulterated or misbranded, but there was no premarketing registration mechanism. Insecticide Act, 1910, ch. 191, 36 Stat. 331 *et seq.*

[3] In 1970, the responsibility for administering FIFRA was transferred to the new Environmental Protection Agency. Reorg. Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).

or, if that failed, by an EPA order that was subject to judicial review. Pub. L. No. 92-516, § 3, 86 Stat. 980. Congress's two purposes in enacting these provisions were to encourage market entry by competitors who otherwise might be discouraged by the high costs of producing health and safety data, and at the same time, to preserve incentives for companies to engage in the required research. See S. Rep. 92-838, 92d Cong., 2d Sess. 6 (1972); S. Rep. 92-970, 92 Cong., 2d Sess. 12 (1972); S. Rep. 92-838, 92d Cong., 2d Sess. Pt. II 21, 69, 71-73 (1972).

The 1972 Amendments failed to define "trade secrets" and failed to resolve the status of data EPA had already received. The latter question was settled in 1975 when Congress limited the data licensing scheme to data submitted on or after January 1, 1970. Pub. L. No. 94-140, § 12, 89 Stat. 755. The definition of "trade secrets" was left to the EPA Administrator and the courts. It developed, however, that several lower court decisions prevented EPA from considering much previously submitted data when reviewing subsequent applications. *Monsanto*, slip op. 5; S. Rep. 95-334, 95th Cong., 1st Sess. 3, 7 (1977); H.R. Rep. 95-663, 95th Cong., 1st Sess. 18 (1977). In part because of such "trade secret" controversies, "the process of registering new pesticides simply ground to a halt." *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104, 111 (3d Cir.), cert. denied, 452 U.S. 961 (1981). Consequently, in 1978, Congress again amended the statute in an effort to remove the barriers to competitors seeking to enter the market for previously registered products. S. Rep. 95-334, *supra*, at 8, 30-31.

In the Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 *et seq.* (1978 Amendments), Congress abolished the 1972 prohibition on agency consideration of "trade secret" data because it had operated to discourage small potential competitors from entering the market by requiring them to duplicate health and safety tests for products similar to those already registered. Congress was concerned that FIFRA, in practice, acted as a de facto extension of patents beyond the statutory period of protection. See, *e.g.*, S. Rep. 95-334, *supra*, at 8, 30-31.

In order to promote competition and eliminate needless duplicative testing, Congress revamped the registration scheme. The costs of developing testing data are now spread among beneficiaries of the data; at the same time, innovation incentives are provided by exclusive use and compensation provisions that are independent of whatever protections a company may have under the patent law. S. Rep. 95-334, *supra*, at 30-31. Under the 1978 Amendments, applicants are granted a ten-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. 136a(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission, if the applicant offers to compensate the original submitter. § 3(c)(1)(D)(ii), 7 U.S.C. 136a(c)(1)(D)(ii). Data that do not qualify for either the ten-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. § 3(c)(1)(D)(iii), 7 U.S.C. 136a(c)(1)(D)(iii).[4]

[4] These provisions operate independently of the patent laws, so chemicals or products that are patented by the original data submitter may not be copied for 17 years (35 U.S.C. 154).

Congress also modified the compensation provisions, significantly changing EPA's role. Unlike the prior statutory regimen, in which EPA decided the amount and terms of compensation when the data submitter and the subsequent applicant could not agree, the revised statute provides that either party may initiate arbitration proceedings by asking the Federal Mediation and Conciliation Service to designate an arbitrator. § 3(c)(1)(D)(ii), 7 U.S.C. 136a (c)(1)(D)(ii). The statute further provides that the "findings and determination of the arbitrator shall be final and conclusive" and not subject to judicial review "except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator" (*ibid.*).[5]

2. Several large pesticide firms brought this action in 1976 in the United States District Court for the Southern District of New York, challenging the constitutionality of the disclosure provisions of FIFRA, as amended in 1972 and 1975. Following the 1978 Amendments, appellees amended their complaint to allege that both the data consideration and data disclosure provisions took their property in violation of the Fifth Amendment and deprived them of their property without due process of law (Plaintiffs' Fourth Amended Complaint, filed Nov. 20, 1978). The district court granted appellees' motion for a preliminary injunction with respect to all data submitted

[5] Section 3(c)(1)(D)(ii) also provides for sanctions against parties who do not cooperate with the arbitration scheme. If an applicant fails to comply with the terms of a compensation agreement or an arbitration award, its registration is subject to cancellation; if a data submitter fails to participate or otherwise comply, it forfeits its right to compensation (7 U.S.C. 136a(c)(1)(D)(ii)).

prior to the enactment of the 1978 Amendments. *Amchem Products, Inc.* v. *Costle*, 481 F. Supp. 195 (S.D.N.Y. 1979). The Second Circuit reversed, however, concluding that plaintiffs had failed to show a likelihood of success on the merits, and this Court denied a petition for a writ of certiorari. *Union Carbide Agricultural Products Co.* v. *Costle*, 632 F.2d 1014 (1980), cert. denied, 450 U.S. 996 (1981).

Following that round of litigation, appellees stipulated to dismissal with prejudice of their taking claims and their due process claims as to the data consideration provisions (Stipulation and Order, filed Sept. 3, 1981). Thus, two contentions remained: (1) that the disclosure provisions, as applied to data submitted prior to 1978, violated due process, and (2) that the arbitration and compensation provisions were an unconstitutional delegation of legislative authority. After this Court's decision in *Northern Pipeline Construction Co.* v. *Marathon Pipe Line Co.*, 458 U.S. 50 (1982), appellees also maintained that the arbitration and compensation scheme violated Article III of the United States Constitution because the statute impermissibly assigned judicial functions to the arbitrators and limited judicial review (Supplemental Memorandum of Plaintiffs in Support of Motion for Summary Judgment, filed Mar. 3, 1983).

The district court granted appellees' motion for summary judgment on their Article III claim (J.S. App. 5a-20a).[6] The court first rejected the government's contention that any challenge to the compensation and arbitration scheme was not ripe for review

[6] The court also rejected appellees' due process claim against the retroactive application of the disclosure provisions and did not reach the claim of unconstitutional delegation of legislative authority (J.S. App. 14a, 19a).

until a party had suffered concrete injury from the results of a specific arbitration (J.S. App. 15a-16a n.2). In the court's view there was no "profit" in delaying resolution of the issue; the mere "statutory compulsion to seek relief through arbitration" was sufficient to create a concrete case or controversy (*id.* at 16a n.2). On the merits, the court concluded that the arbitration scheme is an "impermissible intrusion on the judiciary" (J.S. App. 19a), relying on this Court's decision in *Northern Pipeline*. Because the statute barred Article III courts from reviewing the arbitrator's decision except in instances of "fraud, misrepresentation, or other misconduct," there was, in the court's view, an "absolute assignment of power" to the arbitrators that violated Article III (J.S. App. 19a).

On the basis of this holding, the district court entered a broad injunction (J.S. App. 25a-26a). Rather than striking down only the limitation on judicial review of the arbitrators' decision, the court declared the entire compensation and arbitration scheme unconstitutional (J.S. App. 25a). Further, the court enjoined the Administrator from "permitting or implementing any use of data where the submitter's compensation is to be determined under the said section 3(c)(1)(D)," *i.e.*, during the 15-year period following submission of the data, save when the original data submitter consents to the use of such data (J.S. App. 26a).

3. The government took a direct appeal to this Court (No. 83-1564) pursuant to 28 U.S.C. 1252 and urged the Court to dispose of the case in accordance with the anticipated decision in *Monsanto*, where the same issues were presented. 83-1564 J.S. 6-13. In *Monsanto*, the district court had declared that the data licensing and disclosure provisions were an unconstitutional taking of property and enjoined their implementation. The court also had held the arbitration and compensation scheme invalid as a violation of Article III. *Monsanto*, slip op. 11. This Court vacated the district court's judgment and sustained the constitutionality of the statute. The Court held that there was no taking as to data submitted prior to October 22, 1972, and after September 30, 1978, but that under certain circumstances, firms that submitted data between those two dates may have a claim for just compensation. *Id.* at 17-25. The Court further held that the district court erred in enjoining implementation of the statute because the Tucker Act, 28 U.S.C. 1491, was available to satisfy any claim for just compensation. *Monsanto*, slip op. 27-30.[7] In addition, the Court concluded that Monsanto's Article III claim was not ripe for review since "Monsanto did not allege or establish that it had been injured by actual arbitration under the statute." *Id.* at 31.

4. The Court then vacated the judgment in the present case and remanded for reconsideration in light of *Monsanto*. Order of July 2, 1984 (No. 83-1564). On remand, appellees amended their complaint and filed motions for reentry of judgment and for a preliminary injunction (J.A. 20-24, 26-31). The amended complaint alleged that one of the appellees, Stauffer Chemical Company, had submitted data to EPA in support of registrations for pesticides containing butylate, that EPA had considered these data without Stauffer's consent in granting a registration application filed by PPG Industries, Inc., for a pesticide containing the same active ingredient, and

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[7] The Court held, however, that a data submitter must first seek satisfaction through the arbitration procedure prescribed by the statute. *Monsanto*, slip op. 29.

that Stauffer had invoked the arbitration provisions of FIFRA against PPG (J.A. 23). Further, the complaint stated that the arbitration panel made an award on June 28, 1983, and that the award was less than Stauffer had demanded (*ibid.*). The amended complaint, however, did not request that the arbitration award be set aside or allege any legal defect in the award, other than the previous claim that the procedure for reaching the award was unconstitutional (J.A. 24).[8] As in the previous complaint, the only requested relief was prospective, *i.e.*, that the statutory provisions be declared unconstitutional and that EPA be enjoined from implementing the data licensing scheme under which compensation could be determined by arbitration (*ibid.*).

Following a hearing, the district court reinstated its judgment. The court concluded that "under the amended complaint the issue [was] ripe as to data submitted by plaintiff Stauffer Chemical Company post-1978 as to which there has been an award by an arbitrator" and that there was no basis for changing its earlier decision (J.S. App. 21a). The judg-

[8] In fact, the award is being attacked in a separate action filed, not by Stauffer, but by PPG (which is not a party to the instant case). *PPG Industries, Inc.* v. *Stauffer Chemical Co.*, Civil Action No. 83-1941 (D.D.C. filed July 7, 1983). PPG's complaint asks that the award be set aside as excessive because the arbitrators awarded Stauffer not only a share of the data development costs but also compensation based on PPG's product sales. PPG also claims that Section 3(c)(1)(D) is unconstitutional under the Due Process Clause, the Taking Clause and Article III. Stauffer has not challenged the award as inadequate; indeed, it has counterclaimed for enforcement of the award. In the alternative, Stauffer has cross-claimed against EPA for a declaration that the statute violates Article III and counterclaimed against PPG for cancellation of PPG's registration and for damages in the amount of the award in the event the statutory compensation scheme is invalidated.

ment, as before, declares the compensation scheme unconstitutional as a violation of Article III and enjoins EPA from permitting or implementing any use of data subject to the compensation scheme except where the data submitter consents to such use (J.S. App. 21a). As a result, the provision for mandatory data licensing is invalidated, and the injunction, if allowed to take effect,[9] would create a right to exclusive use of data submitted after 1969 by all pesticide registration applicants.

SUMMARY OF ARGUMENT

1. Following this Court's remand for reconsideration in light of the decision in *Ruckelshaus* v. *Monsanto Co.*, No. 83-196 (June 26, 1984), the district court reentered its injunction striking down the mandatory data licensing and arbitration provisions of FIFRA. Appellees' challenge to the statute, however, does not present a justiciable case or controversy. The district court erroneously concluded that Article III's requirement of a live controversy was satisfied because one of the appellees, Stauffer Chemical Company, had received an arbitration award in an amount less than it had claimed. The district court ignored the consistent line of this Court's cases that has required plaintiffs to demonstrate that the injury alleged will be redressed by the requested relief. *Allen* v. *Wright*, No. 81-757 (July 3, 1984), slip op. 13; *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982); *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 72-73 (1978); *Simon* v. *Eastern Kentucky Welfare*

[9] On October 9, 1984, this Court stayed the judgment pending disposition of this appeal. No. A-178.

Rights Organization, 426 U.S. 26, 38 (1976). This requirement was not satisfied here. Stauffer did not ask the court below to set aside the award or to grant it the greater amount it had sought in the arbitration. In short, Stauffer did not request the only relief that could possibly redress the injury upon which it asserts standing to bring this action.

Since appellees seek no relief from a past arbitration, there is no showing of a threat of a real and immediate injury sufficient to satisfy Article III. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 105-107 (1983); *O'Shea* v. *Littleton*, 414 U.S. 488, 495-496 (1974); *Golden* v. *Zwickler*, 394 U.S. 103, 109 (1969). The fact that Stauffer participated in one such proceeding does not create a sufficient likelihood that that event will occur again. Because the complaint seeks only prospective relief Stauffer is in no different position than that of any of the other appellees who failed to allege even that they had been parties to an arbitration proceeding. The Court's recent decision in *Monsanto* precludes any challenge by such plaintiffs.

2. Even if this case were justiciable, the Article III claim would have to be rejected on its merits. The district court mistakenly relied for its judgment on this Court's recent decision in *Northern Pipeline Construction Co.* v. *Marathon Pipe Line Co.*, 458 U.S. 50 (1982). In fact, however, *Northern Pipeline* expressly states that when Congress creates a statutory right, it may establish "particularized tribunals * * * to perform the specialized adjudicative tasks related to that right." 458 U.S. at 83. In FIFRA, Congress has done precisely that.

The common ground of the Justices concurring in the Court's judgment in *Northern Pipeline* was that Congress could not vest an Article I court with the

adjudication of traditional common law rights that arose entirely under state law. 458 U.S. at 91. In sharp contrast, data compensation disputes under FIFRA were unknown to the common law and are wholly a matter of recently created federal statutory rights. *Northern Pipeline*, accordingly, neither compels nor supports the district court's decision.

FIFRA's pesticide registration program was the result of Congress's effort to promote public health and to facilitate competition (while providing certain entitlements for innovators). The statute thus creates relationships between original registrants and me-too applicants that would not otherwise exist. Specifically, there would be no entitlement to compensation from subsequent applicants for the same or similar pesticide unless FIFRA so provided. When the operation of the registration scheme is properly understood—and the limited role of the arbitration procedure is placed in context—it is clear that Congress has merely created a remedy to "vindicate [the] statutory right to obtain compensation" in specified circumstances, as this Court stated in *Monsanto*, slip op. 31. Congress plainly possesses the authority to do so.

3. Finally, even if the district court had been correct in finding a violation of Article III, no justification would exist for the injunction it entered. The court's order in effect strikes down the entire data licensing scheme. But, since there could be no doubt under *Monsanto* that the scheme would be constitutional if sufficient Article III judicial review were available, the only appropriate relief would be to strike the statute's limitation on review. FIFRA's severability clause, 7 U.S.C. 136x, provides that the invalidation of any provision of the statute is to have

no effect on other provisions. Moreover, this Court has held that any statutory provision is presumptively severable if the remaining portions of the statute are fully operative as a law. *INS* v. *Chadha*, No. 80-1832 (June 23, 1983), slip op. 13. The legislative history gives no indication that Congress would have abandoned the entire data licensing scheme if it had known that compensation disputes would have to be resolved in judicial proceedings. Accordingly, the district court failed in its duty to save and not to destroy the remainder of the statute.

ARGUMENT

I. THE CONSTITUTIONAL CHALLENGE TO FIFRA'S COMPENSATION AND ARBITRATION SCHEME PRESENTED IN THIS LAWSUIT DOES NOT CREATE A JUSTICIABLE CASE OR CONTROVERSY

When last confronted with the identical claim that FIFRA's arbitration and compensation scheme is unconstitutional as a violation of Article III, this Court ruled that the plaintiff in that case, Monsanto, had not presented a ripe claim because it had neither alleged nor established any injury by an actual arbitration under the statute. *Monsanto*, slip op. 31. On remand for reconsideration in light of *Monsanto*, the district court in the present case concluded that Stauffer's claim was ripe because that company was "aggrieved by EPA's use of its data, by the compulsion to resort to an unconstitutional arbitration process * * * and by the arbitration award it had received * * *" (J.S. App. 3a-4a). These allegations and findings are not sufficient to satisfy the requirements of Article III.

A. Article III does not grant to the federal courts a roving commission to determine the constitutionality of every congressional enactment; rather it grants a power that is legitimately exercised "'only in the last resort, and as a necessity in the determination of real, earnest and vital controversy.'" *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982) (quoting *Chicago & G.T. Ry.* v. *Wellman*, 143 U.S. 339, 345 (1892)). "[T]he 'case or controversy' requirement defines with respect to the Judicial branch the idea of separation of powers on which the Federal Government is founded," *Allen* v. *Wright*, No. 81-757 (July 3, 1984), slip op. 12; *Valley Forge*, 454 U.S. at 473-474, and "'assure[s] that concrete adverseness which sharpens the presentation of issues upon which the Court so largely depends for illumination of difficult constitutional questions.'" *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 72 (1978) (quoting *Baker* v. *Carr*, 369 U.S. 186, 204 (1962)).

To satisfy Article III, the appellees must show, at a minimum, that they have suffered (or are threatened with) an actual injury fairly traceable to the challenged conduct of the defendant and that the requested relief is likely to redress the claimed injury. *Allen* v. *Wright*, slip op. 13, 15 n.19 (Brennan, J., dissenting); *Valley Forge*, 454 U.S. at 472; *Duke Power Co.*, 438 U.S. at 72-74, 81; *Simon* v. *Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 38, 41 (1976); *Warth* v. *Seldin*, 422 U.S. 490, 498-499 (1975). Moreover, the claimed injury must be "distinct and palpable," *Warth* v. *Seldin*, 422 U.S. at 501, and not merely abstract or conjectural. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 101-102 (1983); *O'Shea* v. *Littleton*, 414 U.S. 488, 496 (1974); *Golden* v. *Zwickler*, 394 U.S. 103, 109-110 (1969).

The principal error committed by the district court was its failure to require that the requested relief redress the claimed injury. In effect, the district court treated the allegation that Stauffer had been a party to an arbitration as a "free pass" to litigate in the federal courts even though it was conceded that the arbitration was unrelated to any request for relief.[10] Appellees allege merely that one of them—Stauffer—had been awarded less than the amount claimed.[11] This may well have established a basis for a showing of concrete injury to Stauffer. Had Stauffer filed an action in which it sought to remedy the perceived shortfall in its award, it might then have standing and a justiciable claim.

But that is not this case. Indeed, far from seeking to augment its arbitration award, Stauffer has at every opportunity sought merely to preserve that award unchanged. Completely absent from the forms of relief requested by the complaint, or granted by the district court, is any remedy that would alter the arbitrators' decision. In the terminology of Article III analysis, Stauffer seeks no remedy that would redress its perceived injury. The complaint requests a

[10] Appellees informed the district court that they "do not challenge the result of any arbitration, nor does the adjudication of [appellees'] claim depend in any manner on the outcome of an arbitration." J.A. 30.

[11] The arbitrators awarded Stauffer $1,465,000 (one-half of its testing costs), plus "running compensation" for every pound of butylate sold by PPG from 1983 through 1992 (at an adjustable rate approximating 15 cents per pound). J.A. 52, 54. Thus, Stauffer was awarded far more than a division of its test costs even though its original claim exceeded the award. J.A. 23.

declaration that the statutory provisions are unconstitutional and an injunction barring the future implementation of the data licensing scheme when the determination of compensation is subject to the arbitration provision (J.A. 24). Most tellingly, in the pending action brought by PPG for review of the award, see note 8, *supra*, Stauffer has counterclaimed for *enforcement* of that very arbitration award and, in the alternative, has counterclaimed for damages from PPG *in the amount of the arbitration award* in the event the statutory compensation scheme is invalidated.

No matter how "aggrieved" Stauffer may purport to be in some abstract sense, it has neither suffered nor sought to remedy a concrete injury of the sort Article III requires. Indeed, the subsequent actions of the parties to the Stauffer-PPG arbitration clearly show that Stauffer prevailed for all practical purposes. Stauffer has resisted PPG's efforts to overturn the arbitrators' decision, and it steadfastly has chosen not to pursue any remedies that would rectify any wrongs it claims to have suffered—such as seeking to have the award set aside in favor of a judicial resolution of Stauffer's claim against PPG.[12] Accordingly, Stauffer has not " 'alleged such a personal stake in the outcome of the controversy' " as to justify the invocation of the federal judicial power on its behalf. *Simon* v. *Eastern Kentucky Welfare*

[12] In the absence of such an effort, Stauffer's complaint amounts merely to an allegation that the Constitution has been violated. As in *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, *supra*, it is Stauffer's burden "to identify any personal injury suffered by [it] *as a consequence* of the alleged constitutional error * * *." 454 U.S. at 485 (emphasis in original).

Rights Organization, 426 U.S. at 38 (quoting *Warth* v. *Seldin*, 422 U.S. at 498-499).[13]

B. Because appellees seek prospective relief only, relating solely to potential future arbitrations, they are in no better position than was the plaintiff in *Monsanto*.[14] This Court there held (slip op. 31) that there was no justiciable controversy over the constitutionality of the arbitration provision. The fact that Stauffer went through the arbitration process once does not increase the likelihood that that event will occur again; consequently, that fact does not create a real and immediate threat of injury sufficient to confer standing on Stauffer. *City of Los Angeles* v. *Lyons*, 461 U.S. at 105-107; *O'Shea* v. *Littleton*, 414 U.S. at 488, 495-496; *Golden* v. *Zwickler*, 394 U.S. at 109.

II. THE ASSIGNMENT OF THE RESOLUTION OF DATA COMPENSATION DISPUTES TO ARBITRATION WITH LIMITED JUDICIAL REVIEW DOES NOT OFFEND THE CONSTITUTIONAL REQUIREMENTS OF ARTICLE III

The district court, relying on this Court's decision in *Northern Pipeline Construction Co.* v. *Marathon Pipe Line Co.*, *supra*, held that the mandatory arbi-

[13] As this Court stated in *Monsanto*, "[t]he operation of the arbitration procedure affects *only* [the data submitter's] ability to vindicate its statutory right to obtain compensation from a subsequent applicant." Slip op. 31 (emphasis added).

[14] Of course, the appellees other than Stauffer are in precisely the same position as Monsanto and as in *Monsanto*, their challenge should not be permitted to proceed. Those appellees have not become entitled to any compensation and have not engaged in arbitration. *Monsanto*, slip op. 31. See *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 304-305 (1979); *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 164 (1967).

tration provisions of FIFRA were "an impermissible intrusion on the judiciary" because the "system utterly deprives the federal courts of any meaningful role in ensuring the provision of fair compensation to data submitters" (J.S. App. 19a-20a). This result rests on a misinterpretation of the holding in *Northern Pipeline* and on a misapprehension of the limits on Congress's authority to create statutory entitlements and to prescribe the procedures for their implementation—procedures which effectively serve as part of the definition of the statutory entitlement conferred.

Where such a procedure has been deemed to promote legislative objectives, the states and Congress have frequently provided for final and binding arbitration of various kinds of disputes. This Court has upheld such laws against due process challenges. *Hardware Dealers Mutual Fire Insurance Co.* v. *Glidden Co.*, 284 U.S. 151, 157-158 (1931) (state statute mandating arbitration of the amount of loss under insurance policy). See *Crane* v. *Hahlo*, 258 U.S. 142 (1922) (damage awards for municipal construction work reviewable only for jurisdictional defects, fraud, or willful misconduct). See also *Andrews* v. *Louisville & N.R.R.*, 406 U.S. 320 (1972); *Switchmen's Union* v. *National Mediation Board*, 320 U.S. 297 (1943); *Ludwig Honold Mfg. Co.* v. *Fletcher*, 405 F.2d 1123 (3d Cir. 1969); *Edwards* v. *St. Louis-S.F.R.R.*, 361 F.2d 946 (7th Cir. 1966). The question in this case is whether Article III bars Congress's decision to use this arbitration process in resolving data compensation disputes under FIFRA. We submit it does not.

A. The Decision In *Northern Pipeline Co.* v. *Marathon Pipe Line Co.* Does Not Support The District Court's Decision

In *Northern Pipeline*, the Court faced a challenge to the jurisdictional provisions of the Bankruptcy Act of 1978, 11 U.S.C. 101 *et seq.* Prior to 1978, federal district courts served as bankruptcy courts but proceedings in bankruptcy cases generally were held before bankruptcy referees appointed by the district court, unless the district court chose to withdraw the case from the referee. See Bankruptcy Rule 102. Bankruptcy courts were vested with "summary jurisdiction," which extended to controversies involving property in the actual or constructive possession of the court; they did not, however, have "plenary" jurisdiction over disputes involving property in the possession of a third person, except by consent. See *Northern Pipeline*, 458 U.S. at 53.

The 1978 Bankruptcy Act abolished the referee system and established in each district a new United States Bankruptcy Court. 28 U.S.C. 151(a). The judges of the new bankruptcy courts were to be appointed for limited terms by the President, with the advice and consent of the Senate; the judges were also subject to removal by the Judicial Council of the circuit for incompetence, misconduct or disability. 28 U.S.C. 152 and 153.

The 1978 Act also eliminated the distinction between summary and plenary jurisdiction; the statute vested the bankruptcy courts with jurisdiction "of all civil proceedings arising under Title 11 [the Bankruptcy Title] or arising in or related to cases under Title 11." 28 U.S.C. 1471(b) and (c). The *Northern Pipeline* case arose when that company filed a reorganization petition in the United States Bankruptcy Court for the District of Minnesota. 458 U.S.

at 56. Subsequently, Northern Pipeline filed a breach of contract action under state law against Marathon Pipeline Company in the bankruptcy court. *Ibid.* Marathon contested the jurisdiction of the bankruptcy court to adjudicate the state law claim, contending that Article III required that the tribunal resolving this claim consist of judges who had life tenure and protection against salary diminution. 458 U.S. at 56-57. The district court granted Marathon's motion to dismiss and this Court affirmed. *Id.* at 57, 88.

The vice of the 1978 Act was the assignment to the bankruptcy courts of the authority to adjudicate traditional common law rights (458 U.S. at 81-86).[13] The Court did not suggest that the same result would obtain in the situation presented by a mechanism for implementing statutorily-created rights of recent vintage, such as in the situation presented by FIFRA. Indeed, the plurality in *Northern Pipeline* reaffirmed Congress's authority to proceed in this manner (*id.* at 83 (footnote omitted)):

> [W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right

[13] The plurality opinion in *Northern Pipeline* employed a restrictive analysis of the constitutional power of Congress to create legislative courts to adjudicate such rights (458 U.S. at 63-76). In the plurality's view, the Court's prior cases had confined to three the exceptions for this purpose from the requirements of Article III: (1) courts for the territories of the United States and the District of Columbia, (2) courts-martial and (3) cases involving "public rights." *Id.* at 64-70. Adjudication of the state-created right to recover contract damages at issue in *Northern Pipeline* did not fall into any of these three exceptions. *Id.* at 71.

> must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

This statement clearly removes from FIFRA any Article III cloud.[16]

In a separate opinion concurring in the judgment only, Justice Rehnquist, joined by Justice O'Connor, did not endorse the plurality's analysis (see note 15, *supra*), stating that the "confusing precedents" were not subject to "easy synthesis." 458 U.S. at 90-91. In Justice Rehnquist's view, it was sufficient that no case had gone so far as to permit Congress to assign to a non-Article III forum the adjudication of a traditional action at common law that arose entirely under state law. 458 U.S. at 90-91.

The *Northern Pipeline* holding is therefore limited to the proposition that traditional common law rights arising entirely under state law may be adjudicated in the federal system only by Article III courts or in an adjunct system that preserves the essential attributes of judicial power in an Article III court. See 458 U.S. at 92 (Burger, C.J., dissenting). The case at bar does not involve traditional common law rights at all, let alone such rights arising entirely under state law. Under FIFRA, the arbitrator determines the amount of compensation due a data submitter, the entitlement to which is created solely by the congressionally-mandated data licensing scheme for registering pesticides. *Monsanto*, slip op. 31. The decision in *Northern Pipeline*, therefore, does not

[16] The plurality also rejected the contention that Article III was satisfied because the bankruptcy courts were merely adjuncts of the district courts. 458 U.S. at 76-87. See also *id.* at 91 (Rehnquist, J., concurring in the judgment).

support invalidation of FIFRA's arbitration provisions.

B. The Entitlement To Compensation Under FIFRA Is Wholly A Statutory Creation

This Court stated in *Monsanto* (slip op. 31) that the arbitration procedure "affects only Monsanto's ability to vindicate its statutory right to obtain compensation from a subsequent application whose registration application relies on data originally submitted by Monsanto * * *." That correct statement of the role of FIFRA's arbitration procedure distinguishes this case from *Northern Pipeline*. In the absence of FIFRA, the right to compensation would not exist; nor for that matter would the relationships that give rise to that right.

If FIFRA were repealed, companies would be free to market pesticides without any premarket review; no registration would be necessary. Competitors would be free to market copies of appellees' unpatented end-products, without any necessity of duplicating appellees' testing (if any were performed).[17] These competitors would simply enter the market and appellees would be entitled to no compensation—no sharing of the costs of testing. And, hypothetically, instead of enacting FIFRA, Congress could have required registration, supported by testing data, only of new pesticide products, which (if unpatented) could then freely be copied by other manufacturers.[18]

[17] Rights under the patent law are, of course, unaffected by FIFRA.

[18] This is the method of accommodating interests in public health, innovation, and competition in the Food and Drug Administration's approval systems for food additives and color additives. These call for premarketing submissions only by the pioneer company; competitors need obtain no approvals before marketing copies of an approved product (21 U.S.C.

Again, there would be no compensation of the sort to which FIFRA creates an entitlement.

On the other hand, Congress could have established a scheme that barred EPA from considering previously submitted data, thus requiring each applicant for registration to submit its own data. As the legislative history demonstrates, Congress eschewed any of these extreme alternatives in fashioning a workable registration system that protects the public health (by requiring submission of data that will enable EPA to determine that a pesticide will not cause "unreasonable adverse effects on the environment," § 3(c)(5)(D), 7 U.S.C. 136a(c)(5)(D)), and promotes competition (by enabling competitors to market copies of unpatented pesticide products more quickly by avoiding duplication of testing data). At the same time, it provides for a sharing by subsequent applicants relying on the original registrant's test data of the cost of generating those data. FIFRA's legislative history shows that the compromise reflected in the data consideration and compensation provisions was the result of a careful weighing of burdens and benefits.

As this Court noted in *Monsanto*, slip op. 26, Congress enacted the data licensing and compensation scheme to alleviate the anticompetitive effects of FIFRA's data requirements. After much debate, Congress decided to encourage competitors to enter the market by permitting EPA to grant "me-too" registrations on the basis of data submitted by another firm manufacturing the same or similar pesti-

348(a)(2), 376(a)(1)). And, "[a]ll safety and functionality data and information submitted" by the pioneer company are "available for public disclosure" (21 C.F.R. 71.15, 171.1(h)).

cide. See S. Rep. 92-970, *supra*, at 12; S. Rep. 92-838, *supra*, Pt. II at 69, 71-73. But Congress also wanted to encourage research and development, and concluded that compensation for the use of test data was an appropriate incentive for innovation. See S. Rep. 92-838, *supra*, Pt. II at 71-73.[19]

Since Congress decided to require mandatory data licensing and grant compensation for this use of a company's research data, Congress also had to decide how the compensation would be determined if the parties could not reach agreement. In the 1972 Amendments, Congress placed EPA in the role of the initial arbiter, and provided for on-the-record administrative proceedings. 86 Stat. 980. The right to appeal to the courts was limited, since only the data submitter could seek review and the court could not reduce the amount of compensation awarded in the administrative proceedings. *Ibid.* Difficulties arose, however, in the implementation of this scheme, principally because of uncertainty whether "trade secret" data and data submitted prior to 1972 were subject to the compensation requirements. See S. Rep. 94-452, 94th Cong., 1st Sess. 10-11, 15 (1975). In addition, the delay in determining compensation had apparently slowed the registration process. The 1975 Amendments set a cut-off date of January 1, 1970, and also provided that "[r]egistration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court." 89 Stat. 755.[20]

[19] The compensation provision was also viewed as a fair way to spread the costs of data development. S. Rep. 92-838, *supra*, Pt. II at 69.

[20] The 1975 Amendments also permitted both parties to seek judicial review. 89 Stat. 755.

As this Court noted in *Monsanto*, by 1978 Congress found that the registration process was mired in a complex set of controversies about data protection, "trade secrets," and compensation rights. See *Monsanto*, slip op. 4-5; H.R. Rep. 95-663, 95th Cong., 1st Sess. 18, 21, 41-42, 53, 58-59 (1977); S. Rep. 95-334, 95th Cong., 1st Sess. 3, 7, 30-31 (1977). Specifically, Congress was concerned that the court's broad reading of the "trade secret" provisions had exempted a large volume of data from the licensing scheme and had discouraged market entry. In addition, Congress was informed that the structure of the data compensation procedure had also contributed to the frustration of the statute's purposes. The Administrator of EPA told the House Committee on Agriculture that potential market entrants "object to signing a 'blank check' for use of data—that an offer to pay reasonable compensation without knowing what that means in terms of dollars and cents is unpalatable from a business point of view." H.R. Rep. 95-663, *supra*, at 59. The Administrator also told Congress that determination of the appropriate amount of compensation was outside the agency's area of expertise (*ibid.*).[21]

The Senate Committee on Agriculture, Nutrition and Forestry concluded that the data licensing and compensation scheme was "essential to the registration process" but that "administration of this [scheme had] been plagued with problems." S. Rep. 95-334, *supra*, at 7. In part, the Committee sought to solve those problems by relieving EPA of the burden of adjudicating compensation disputes and by establishing a system of binding arbitration. S. Rep. 95-334, *supra*, at 8.[22] To address these urgent concerns identified by Congress, the 1978 Amendments imposed the requirement of binding arbitration of data compensation disputes by arbitrators supplied by the Federal Mediation and Conciliation Service; the amendments also provided for judicial review in instances of "fraud, misrepresentation, or other misconduct." 7 U.S.C. 136a(c)(1)(D)(ii).

The history of Congress's effort to devise an efficient and workable pesticide registration system shows that in 1978 the need to simplify and expedite that process was acute. Among the important issues facing Congress was the creation of a mechanism for resolving compensation disputes. It is evident that the resolution of such disputes presented only narrow questions peculiar to the economics of conducting research on the environmental and health effects of pesticides. Congress correctly perceived that prompt resolution of these disputes was an important factor in facilitating the registration of the products of potential competitors. Congress also concluded that burdening EPA with the initial determination was a hindrance to expeditious settlement of these claims. The legislative decision to satisfy the particularized need in this specialized area by selecting binding arbitration, a dispute resolution measure common in the commercial world, was plainly justified by the situation existing at the time of the 1978 Amendments.

C. Congress Acted Within Its Constitutional Powers In Creating A Remedy For Vindicating A Statutorily Created Entitlement

As we have described, Congress has established certain economic relations between competing pro-

[21] The agency supported the substitution of binding arbitration for the additional reason that it "advanced the probability that data originators will be promptly compensated." H.R. Rep. 95-663, *supra*, at 53.

[22] The Committee also noted that the reforms it proposed would reduce the need for "lengthy data compensation claims." S. Rep. 95-334, *supra*, at 31.

ducers of pesticide products, in an exercise of its constitutional authority to regulate interstate commerce. In the interest of safeguarding the public health while promoting competition and thus benefitting the public at large, Congress has imposed restrictions (that would not otherwise exist) on the ability of competitors to market unpatented pesticide products, but has limited those restrictions by also imposing a form of mandatory data licensing on certain pesticide registrants. Concomitantly, Congress granted subsequent applicants for registrations the right to rely on previously-submitted data *if they pay the statutory price.*[23] That statutory price defines the limit of the first registrant's wholly statutory right to exclude competitors from marketing an unpatented product. There could hardly be a clearer example of the exercise of Congress's constitutional "discretion," in "creat[ing] a statutory right," to "prescribe remedies" and "provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks

[23] The right to rely on data submitted by others is further limited. It does not, of course, afford a right to market a product in violation of a patent. In addition, original applicants are granted a ten-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. 136a(c)(1)(D)(i). See *Monsanto*, slip op. 5. Even in these limited circumstances where previously submitted data may be relied upon without the original applicant's consent, the arbitration process is triggered only when the original registrant and follow-on applicant are unable to agree on the amount of compensation. Only one arbitration has been concluded since FIFRA was amended in 1978.

related to that right." *Northern Pipeline*, 458 U.S. at 83 (plurality opinion).[24]

III. EVEN IF THE ARBITRATION PROVISIONS OF FIFRA VIOLATE ARTICLE III, THE COURT BELOW ERRED IN ITS CHOICE OF RELIEF

Although the only constitutional defect the district court found was the absence of more comprehensive judicial review of arbitration awards, it enjoined the EPA Administrator from implementing the entire data licensing system. The district court order gives data submitters the right to prohibit use of their data during the 15-year period following submission to EPA—exactly the opposite of what Congress intended. This wholesale revision of the congressionally-devised scheme is not only unjustified by the perceived constitutional deficiency but is also directly contrary to FIFRA's express severability provisions.

[24] In *Crowell* v. *Benson*, 285 U.S. 22 (1932), the Court reviewed the worker's compensation scheme created by the Longshoremen's and Harbor Workers' Compensation Act, ch. 509, 44 Stat. 1424. That statute created an administrative and judicial system for the compensation of private employees injured while working on the navigable waters of the United States. 285 U.S. at 37-38. The Court concluded that the adjudication of the compensation liability of a private employer to one of its employees was purely a matter of private rights, and therefore subject to the limitations of Article III.

The situation presented here, however, bears only the most superficial resemblance to the circumstances of *Crowell* v. *Benson, supra*. There, Congress attached liability to a relationship, that of employer and employee, that was entirely the creation of the voluntary conduct of the parties in pursuit of wholly private interests. In contrast, it is the statutory scheme of FIFRA that creates the relationship of original data submitter and subsequent applicant out of which the compensation liability under FIFRA arises.

There could be no doubt that the scheme would be constitutional if an Article III court could correct errors of law and exercise some review of the factual findings, as in the typical case of judicial review of action by a federal administrative agency. See *Northern Pipeline*, 458 U.S. at 83; *Crowell* v. *Benson*, 285 U.S. 22, 50 (1932). See also *United States* v. *Raddatz*, 447 U.S. 667, 683 (1980); *St. Joseph Stock Yards Co.* v. *United States*, 298 U.S. 38, 53 (1936).

The district court could have as effectively remedied any defect it found simply by enjoining the operation of only the portion of Section 3(c)(1)(D)(ii) that states: "the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination * * * except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct." This narrower relief would conform to the intent of Congress, as expressed in FIFRA's severability clause (§ 30, 7 U.S.C. 136x):

> If any provision of this [Act] or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this [Act] which can be given effect without regard to the invalid provision or application, and to this end the provisions of this [Act] are severable.

The data use and compensation provisions of Section 3(c)(1)(D)(ii) *can* "be given effect" without regard to the allegedly invalid provision limiting judicial review. The statute would, as Congress intended, continue to allow applicants for registration to rely on previously submitted data (provided they offer to pay compensation), thus fostering competition and discouraging wasteful duplicative testing. The parties would remain free to resolve controversies about the amount and terms of compensation by negotiation, and to take disputes to arbitration. Only the scope of judicial review of arbitration decisions would be modified, and then only to the extent found necessary to achieve compliance with Article III.

Section 3(c)(1)(D)(ii) confers on persons such as appellees a wholly federal "statutory right to obtain compensation from a subsequent applicant whose registration application relies on data originally submitted by" such persons. *Monsanto*, slip op. 31. If the limitation on judicial review were severed, there would be no barrier to a federal court challenge to a FIFRA arbitration decision that allegedly diminished that right. The aggrieved person would have a cause of action arising under FIFRA either expressly, see *Monsanto*, slip op. 31, or impliedly. District courts would have jurisdiction under 28 U.S.C. 1331 to review arbitration decisions under FIFRA since the challenge would be a civil action "arising under the * * * laws * * * of the United States" that would not be precluded by the valid portions of FIFRA.[25] See *International Association of Machinists* v. *Central Airlines, Inc.*, 372 U.S. 682, 694 & n.18 (1963) (action to enforce award of Adjustment Board under Railway Labor Act is action arising

[25] Aside from the limitation on review of arbitrators' decisions, the only arguably relevant FIFRA jurisdiction provision states that "other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts." FIFRA § 16(a), 7 U.S.C. 136n(a).

under laws of United States with jurisdiction in federal district courts).[26]

Whether a constitutionally invalid provision can be severed from a statute is a matter of congressional intent, *INS* v. *Chadha*, No. 80-1832 (June 23, 1983), slip op. 10-11; *Buckley* v. *Valeo*, 424 U.S. 1, 108-109 (1976); *Tilton* v. *Richardson*, 403 U.S. 672, 682-684 (1971); *Electric Bond & Share Co.* v. *SEC*, 303 U.S. 419, 434 (1938); but the question of intent is presumptively answered by the presence in the statute of a severability clause, *INS* v. *Chadha*, slip op. 11. Moreover, absent express evidence of congressional intent to the contrary, where "what remains after severance 'is fully operative as a law,'" a provision will be "presumed severable," *INS* v. *Chadha*, slip. op. 13, quoting *Champlin Refining Co.* v. *Corporation Commission*, 286 U.S. 210, 234 (1932).

Nothing in FIFRA or its legislative history rebuts these presumptions. As we have shown, pages 30-31, *supra*, if Article III requires broader judicial review the basic scheme would not be unworkable, even if there were some greater delay in the resolution of some compensation issues. There is no indication,

[26] In a case involving a specific challenge to the outcome of an arbitration decision (unlike the situation here, see pages 16-18, *supra*), a plaintiff could assert the appropriate cause of action and identify the basis under which jurisdiction is asserted. For example, in the challenge brought by PPG Industies seeking review of the arbitration decision involving appellee Stauffer, PPG's complaint, Stauffer's counterclaim, and Stauffer's cross-claim all state that jurisdiction over the subject matter is based on, among other sections, 28 U.S.C. 1331. Complaint, Civil Action No. 83-1941 (D.D.C. filed July 7, 1983); Answer, Counterclaim and Cross-Claim of Defendant Stauffer Chemical Company (filed Sept. 6, 1983).

moreover, that if Congress had thought that broader and more time-consuming judicial review was required, it would have jettisoned the entire data licensing scheme.

The data consideration and compensation provisions in Section 3(c)(1)(D)(ii), including the provision for binding arbitration and the limitation on judicial review, were a refinement of the mechanism Congress first developed in 1972. While one purpose of adopting arbitration was to shorten and simplify the compensation-setting process, an equally important purpose was to eliminate the decision-making burden the prior statute had imposed on EPA.[27] The particular means chosen for resolving disputes was not central to the question whether applicants should be able to base their applications upon previously submitted data. Indeed, without the data-licensing scheme, there will be no compensation disputes *needing* resolution.[28] Accordingly, the district court failed

[27] The Senate Report states (S. Rep. 95-334, 95th Cong., 1st Sess. 8 (1977)):

> The reasonableness of compensation is difficult to determine and the Environmental Protection Agency was not established to make such determinations. The Subcommittee agreed that the amount and terms of reasonable compensation would be determined by the parties involved—the original submitter of the data and the later applicant who wishes to rely on it.
>
> The Subcommittee also adopted a provision for binding arbitration under procedures established by the Federal Mediation and Conciliation Service, if the parties fail to agree on compensation.

[28] If, despite our argument, the limitation on judicial review is found not to be severable and Section 3(c)(1)(D)(ii) therefore is found invalid, it remains unclear why the remedy

to fulfill its duty "to save and not to destroy" the remaining portions of the statute. *Tilton* v. *Richardson*, 403 U.S. at 684, quoting *NLRB* v. *Jones & Laughlin Steel Corp.*, 301 U.S. 1, 30 (1937); *Regan* v. *Time, Inc.*, No. 82-729 (July 3, 1984), slip op. 10-11 (opinion of White, J.).[29]

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should be a judicially-crafted substitute scheme that gives data submitters an absolute right to *veto* use of their data. It would be more reasonable to hold that the data formerly governed by Section 3(c)(1)(D)(ii) may be cited without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data, since there would no longer be "any period for which compensation is required for the use of an item of data." FIFRA § 3(c)(1)(D)(iii), 7 U.S.C. 136a(c)(1)(D)(iii).

[29] That duty had been made all the more emphatic by the fact that this Court in *Monsanto* had just sustained the constitutional validity of provisions whose enforcement the district court again saw fit to enjoin.

CONCLUSION

The judgment of the district court should be reversed and the case remanded with instructions to vacate the injunction and to dismiss the complaint.

Respectfully submitted.

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